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20306	7590	10/01/2007	EXAMINER	
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP			FOSTER, CHRISTINE E	
300 S. WACKER DRIVE			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Requirement for Information under 37 CFR 1.105

Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

This requirement is being made by the Examiner because:

- (A) the examiner's search and preliminary analysis demonstrates that the claimed subject matter cannot be adequately searched by class or keyword among patents and typical sources of non-patent literature, and
- (B) either the application file or the lack of relevant prior art found in the examiner's search justifies asking the applicant if he or she has information that would be relevant to the patentability determination.

The amendment filed 7/27/07 presents a step in independent claim 44 of "calculating a test area-specific cut-off index (COI)" (see step (d) of claim 44). Newly added claim 78 recites that the COI is calculated by the formula:

COI = $\frac{\text{signal}_{\text{sample}} - \text{background}_{\text{sample}}}{n} \times \text{background}_{\text{negative control}}$, the n ranging between 2 and 100

The claimed subject matter involving the above equation cannot be adequately searched by traditional means involving class or keyword search. For example, a text-based search of such an equation would not be likely to uncover relevant art since equations may be expressed

graphically in a figure. Furthermore, the same equation may be expressed in multiple ways, for example using different terms to refer to the same variables.

In addition, the above equation is disclosed in the specification at page 22, where it is introduced as a “conventional calculation”. Therefore, the specification describes the equation as being conventional, which may be considered as an admission of prior art. However, this equation is unfamiliar to the examiner and cannot be found within the application file or from the examiner’s search.

Since Applicant now argues that the use of such a cut-off index (COI) distinguishes the claimed invention over the prior art of record (see for example Applicant’s Reply of 7/27/07 at pages 6-8), further details of the information would be relevant to the question of patentability.

The characterization of the equation at issue as “conventional” suggests the applicant likely has access to information necessary to a more complete understanding of the invention and its context.

In response to this requirement, please provide answers to each of the following interrogatories eliciting factual information:

Regarding the equation **COI = signal_{sample}-background_{sample}/n x background_{negative control}**:

1. What is the source of this equation?
2. How was this equation derived, and by whom?
3. Is this equation, or similar calculations of a cut-off index (COI), known in the prior art?
4. Where else is this equation, or similar calculations of a cut-off index (COI), disclosed?

The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.

In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure.

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

This requirement is subject to the provisions of 37 CFR 1.134, 1.135 and 1.136 and has a shortened statutory period of 2 months. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The

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examiner can normally be reached on M-F 8:30-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached at (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CF

Christine Foster, Ph.D.
Patent Examiner
Art Unit 1641

Long Le 09/20/07
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